OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA: 022573	Submission Dates: 11/26/09; 04/28/10; 06/5/10; 12/16/10, 12/21/10
Brand Name	TRADENAME
Generic Name	Norethindrone and Ethinyl Estradiol chewable tablets and ferrous fumarate chewable tablets
Reviewer	Christian Grimstein, Ph.D.
Team Leader	Myong-Jin Kim, Pharm.D.
OCP Division	Division of Clinical Pharmacology 3
OND Division	Division of Reproductive and Urologic Products (DRUP)
Sponsor	Warner Chilcott Company, LLC.
Submission Type	Original/505(b)(1)
Formulation and Strength	Chewable tablets, Cycle Days 1-24: EE 0.025 mg + NE 0.8 mg; Cycle Days 25-28: ferrous fumarate (placebo)
Indication	Prevention of pregnancy

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1 Executive Summary

The Clinical Pharmacology review of NDA 022573 (DARRTS, 09/01/2010) stated that the NDA 022573 was acceptable provided that an agreement is reached between the sponsor and the Division regarding the language in the package insert labeling. The agreement on the language in the package insert labeling between the sponsor and the Division was reached on 12/21/2010. The highlights of the prescribing information and Clinical Pharmacology relevant sections of the final agreed upon package insert labeling are included in Section 2 of this addendum.

1.1 Recommendation

The Division of Clinical Pharmacology 3, Office of Clinical Pharmacology finds the NDA 022573 acceptable.

8 pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

CHRISTIAN GRIMSTEIN
12/21/2010

MYONG JIN KIM
12/22/2010